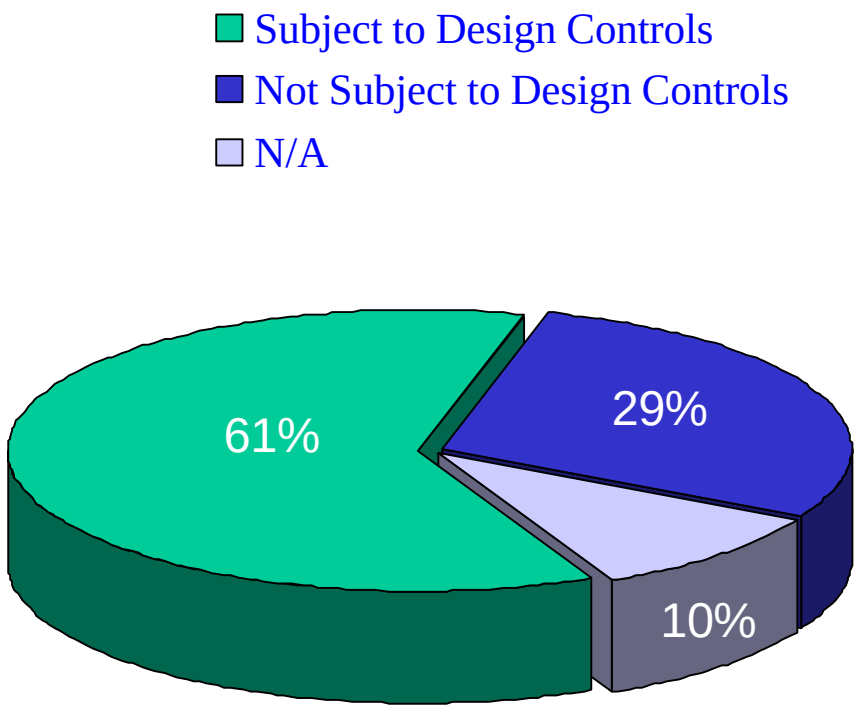
Design Control Inspection Results

June 1, 1997

to

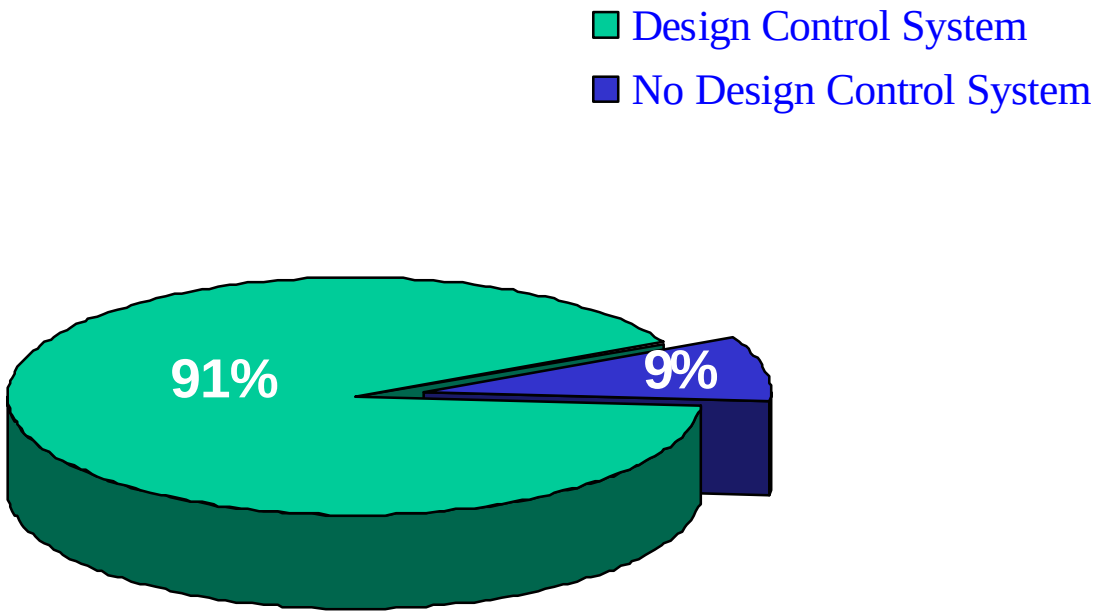
June 1, 1998

Devices Covered



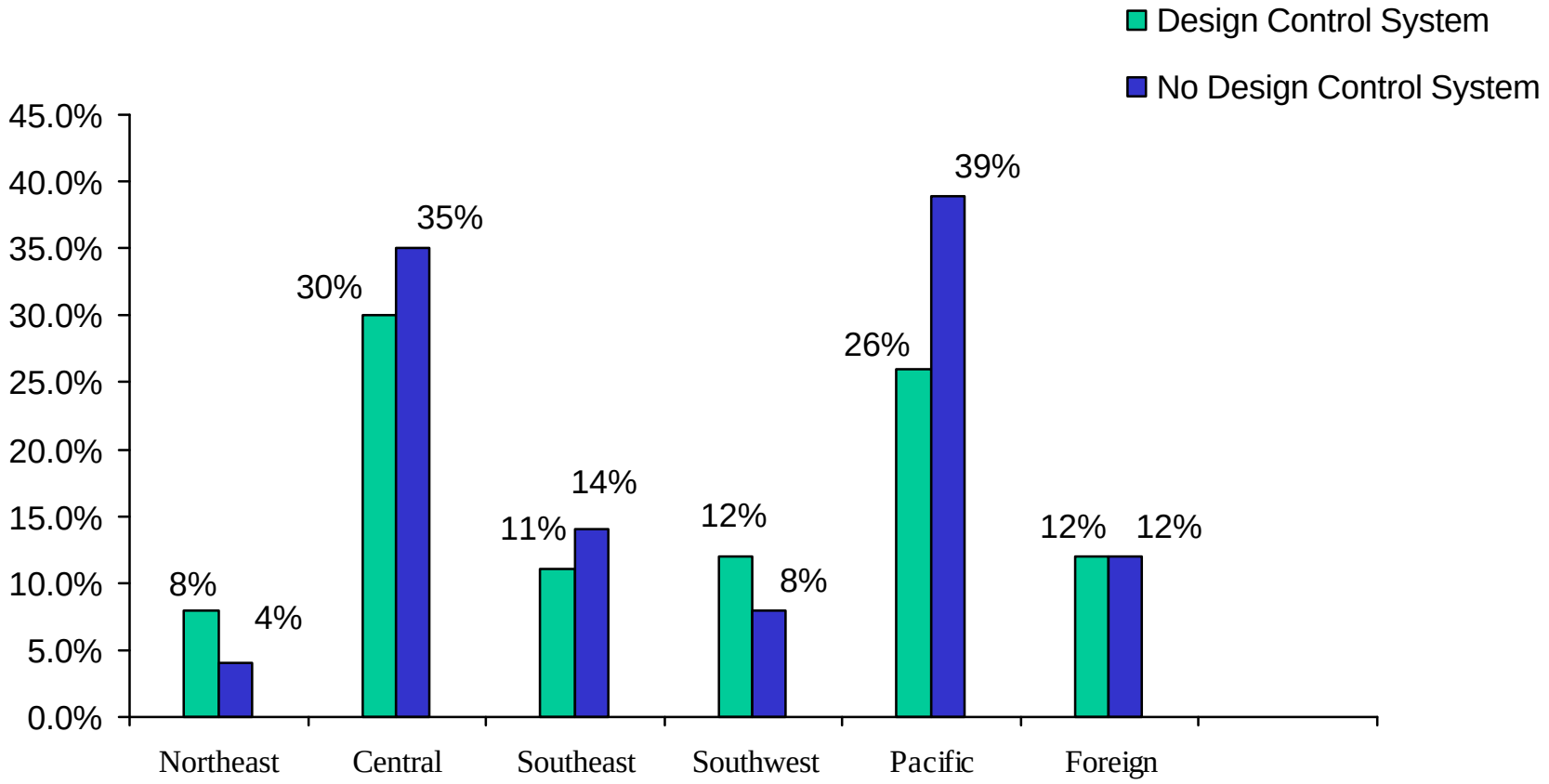
Total Firms = 582

Firms with No Design Control System



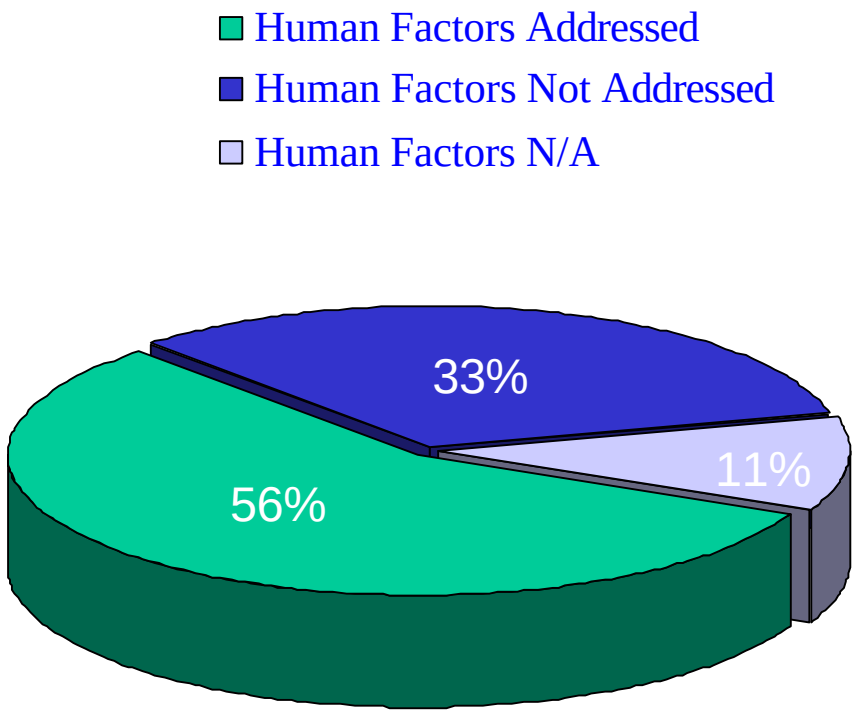
Total Firms = 582

Firms with/without Design Control Systems



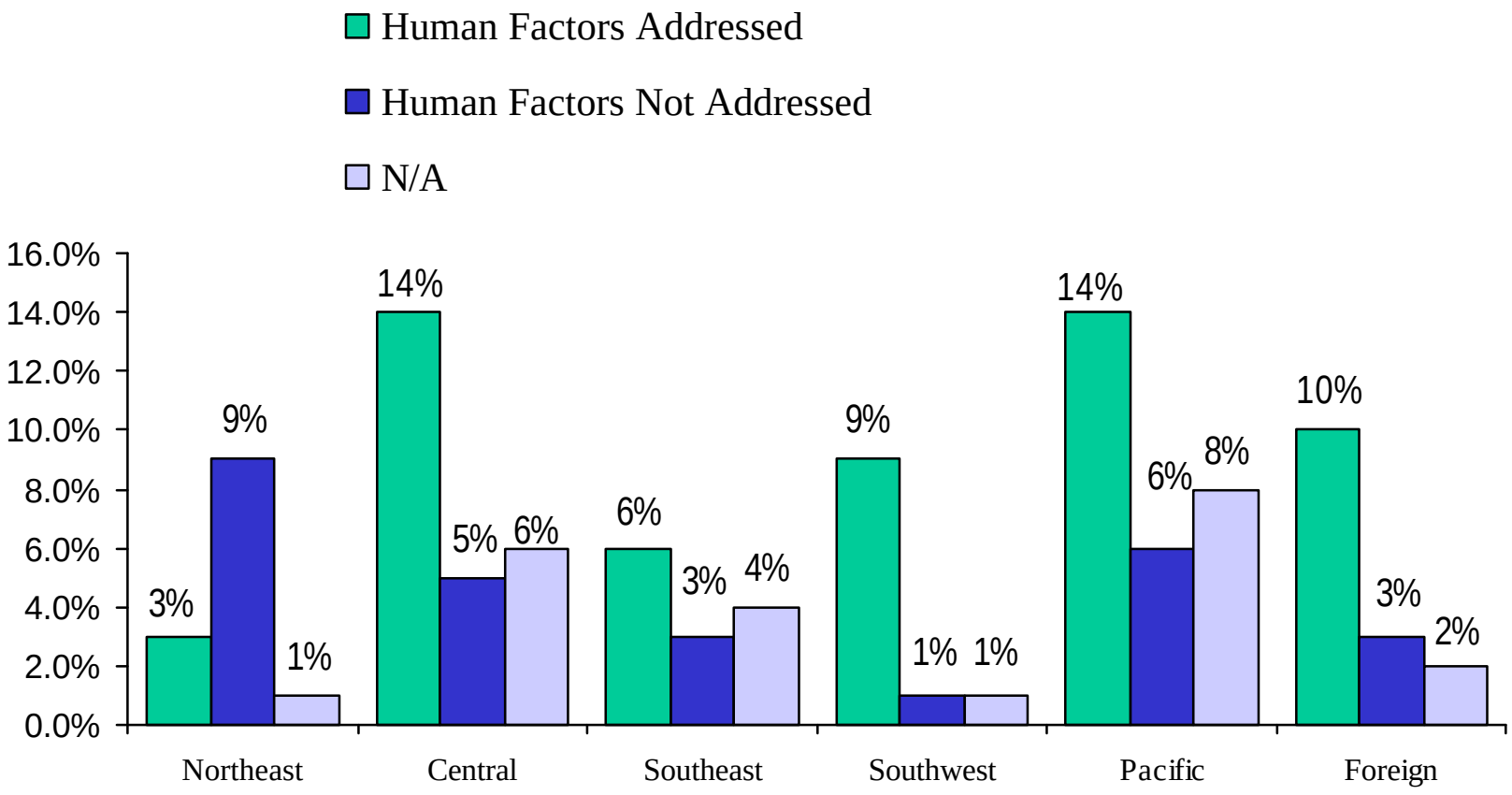
Total Firms = 582

Human Factors



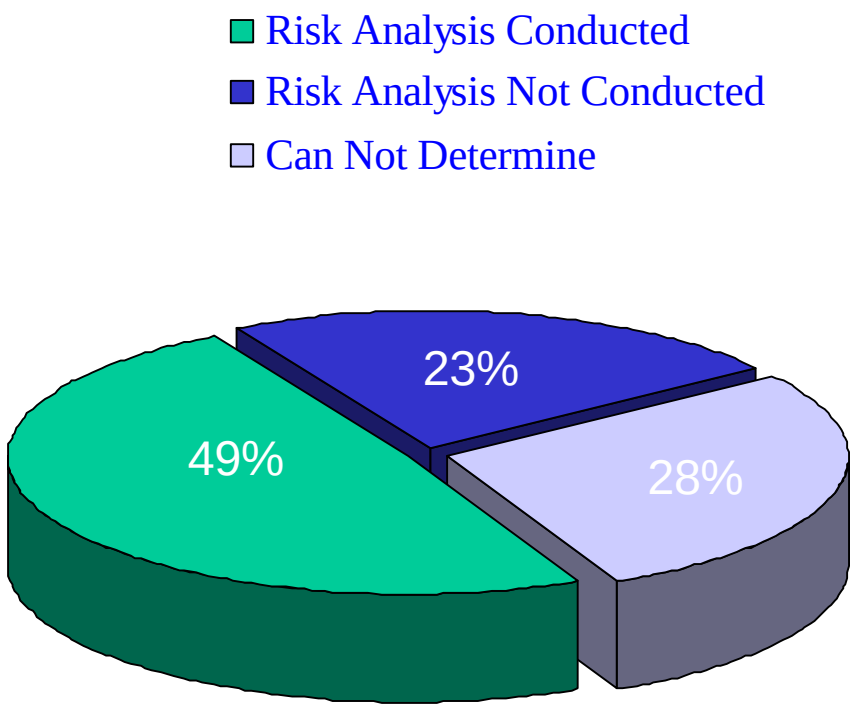
Total Firms = 582

Human Factors



Total Firms = 582

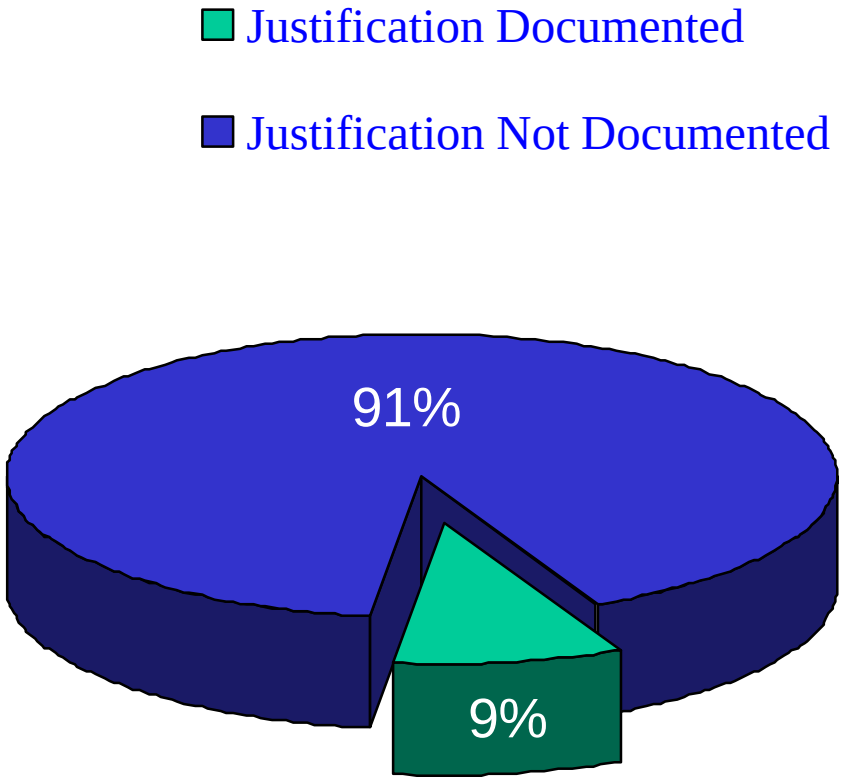
Risk Analysis



Total Firms = 582

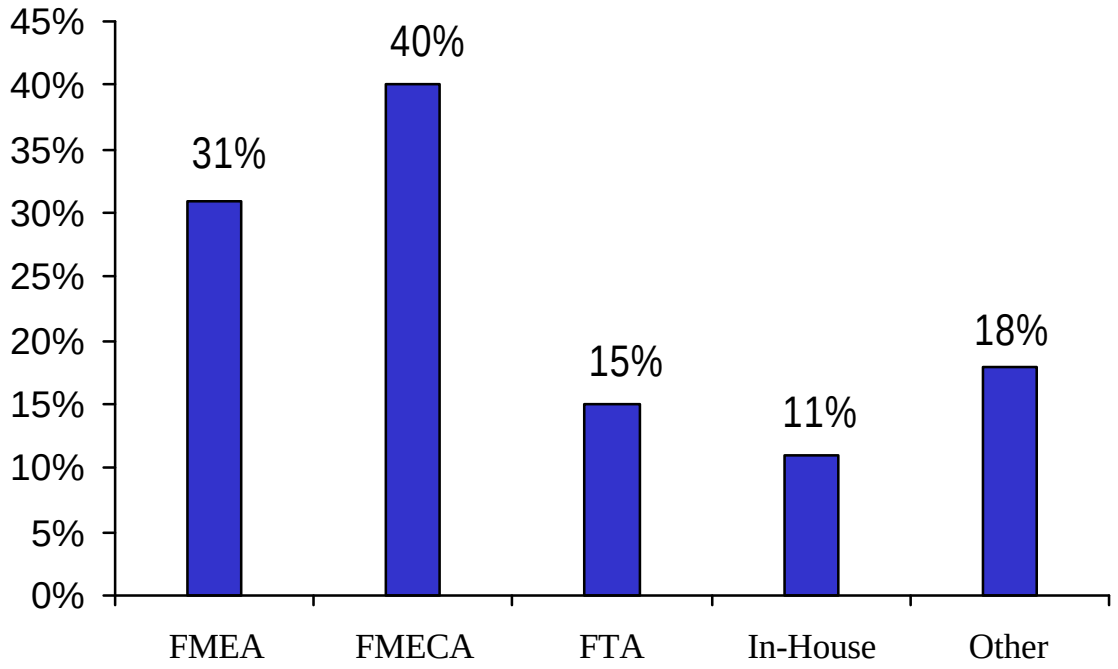
Data Collected from Design Control Inspectional Team Evaluation of Reports

Risk Analysis Not Conducted



Total Firms = 134

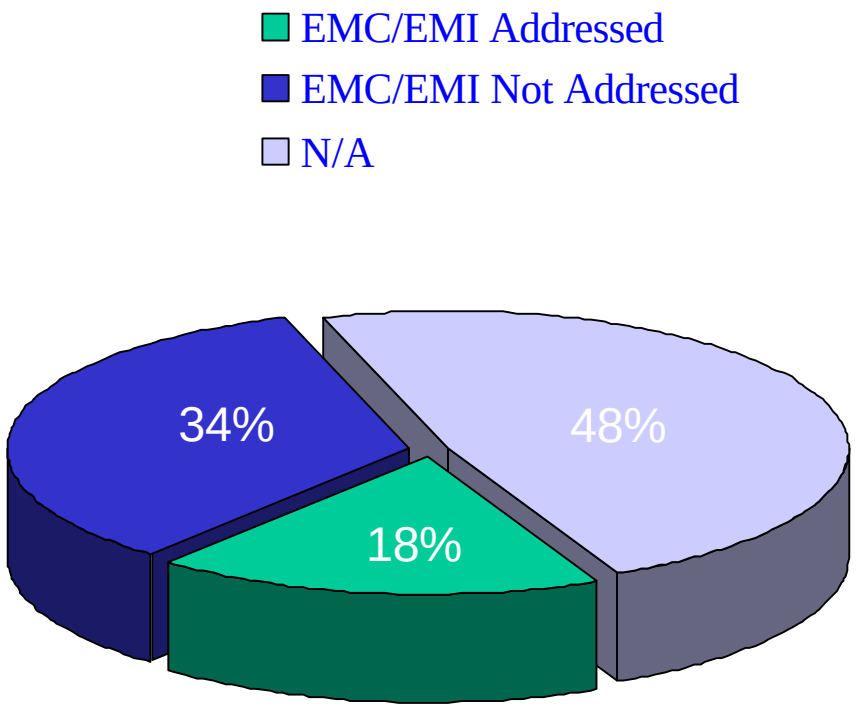
Risk Analysis Techniques Used



Total Records = 285

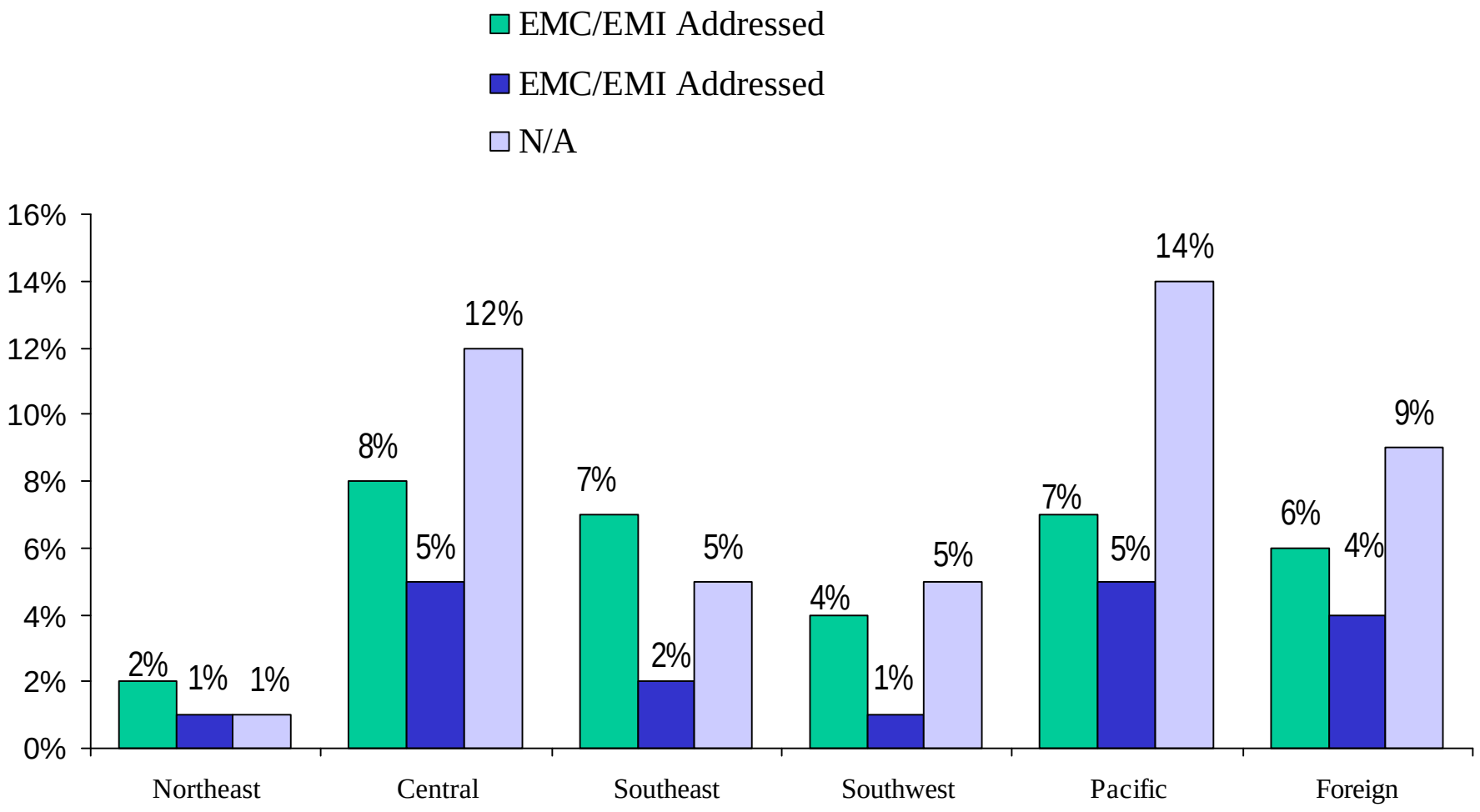
Note: Some firms used more than one technique

Electromagnetic Compatibility/ Electromagnetic Interference



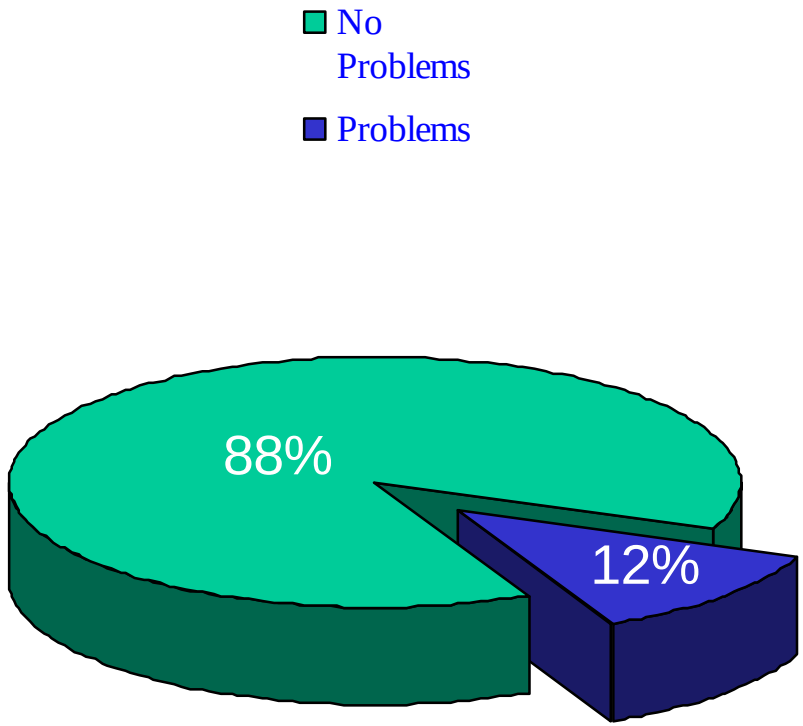
Total Firms = 582

Electromagnetic Compatibility/ Electromagnetic Interference



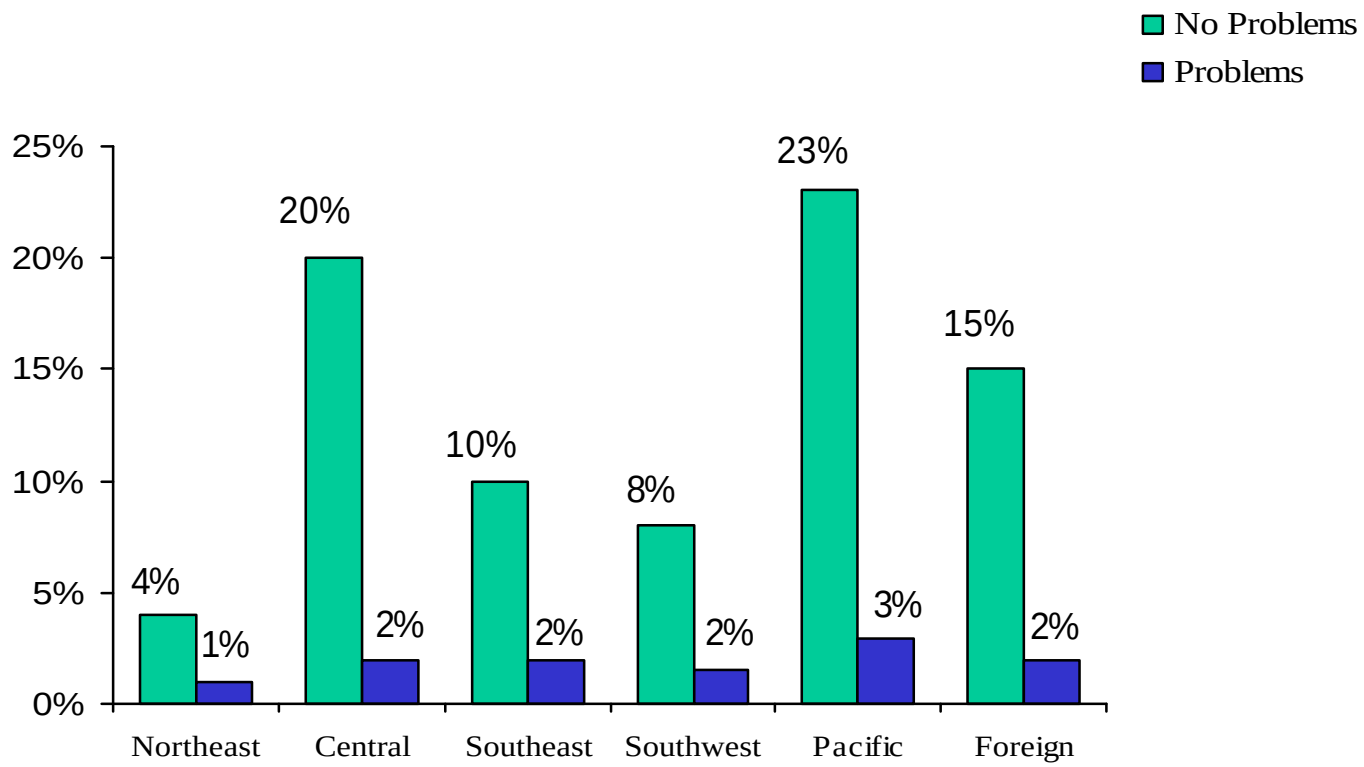
Total Firms = 582

Understanding Design Validation Vs. Process Validation



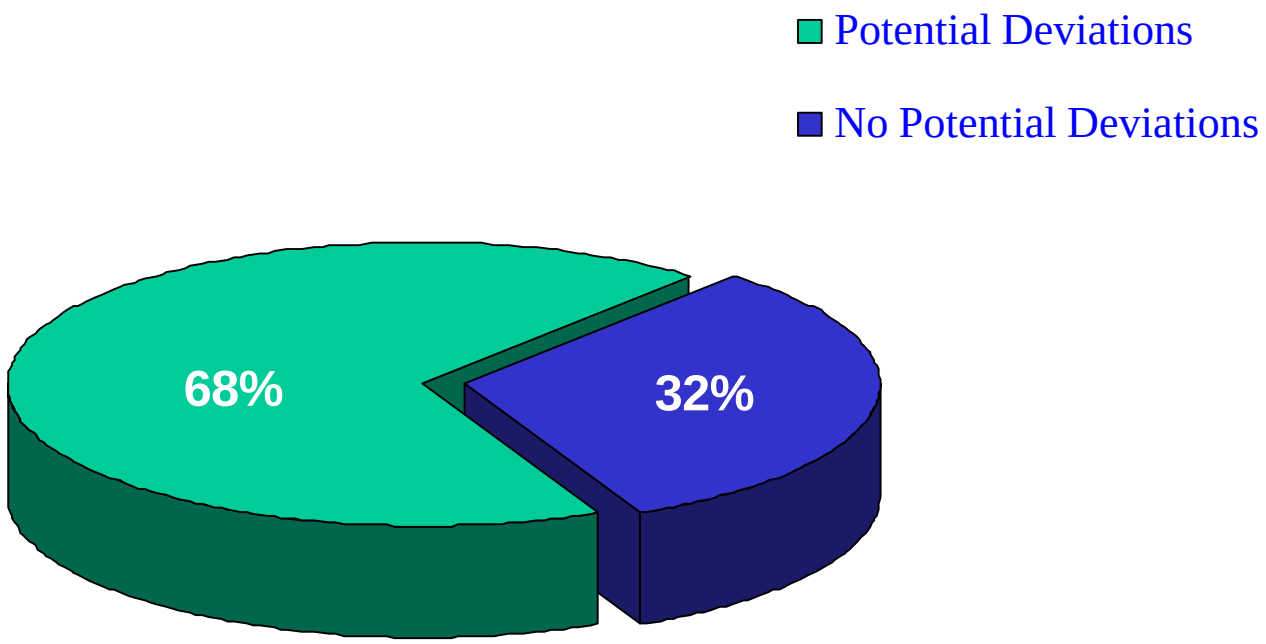
Total Firms = 582

Understanding Design Validation Vs. Process Validation



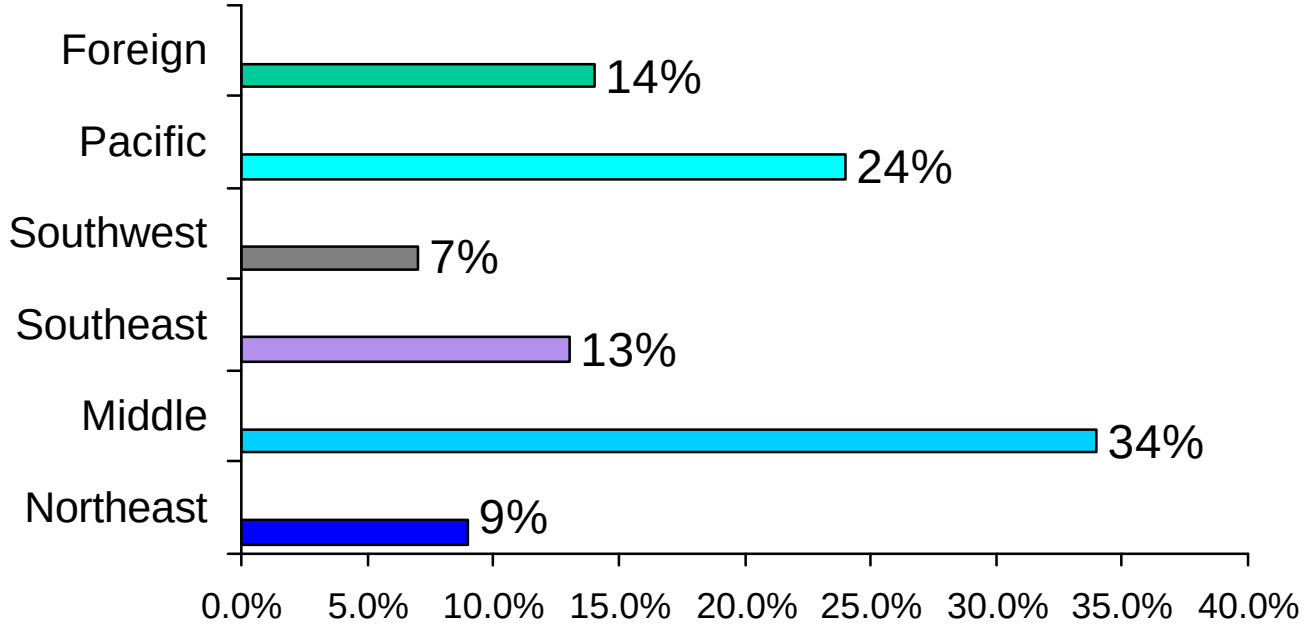
Total Firms = 582

Firms with Potential Design Control Deviations



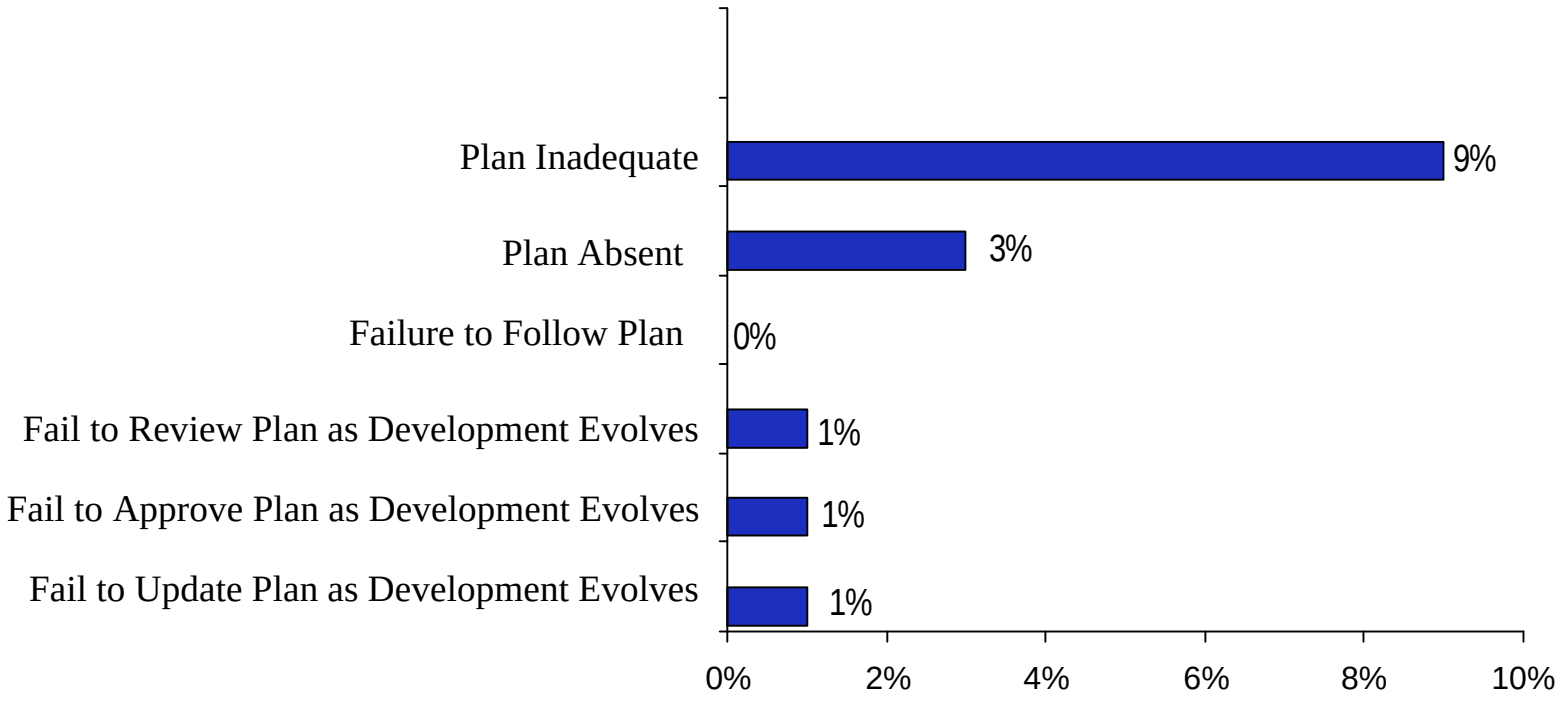
Total Firms = 582

Firms with Potential Design Control Deviations



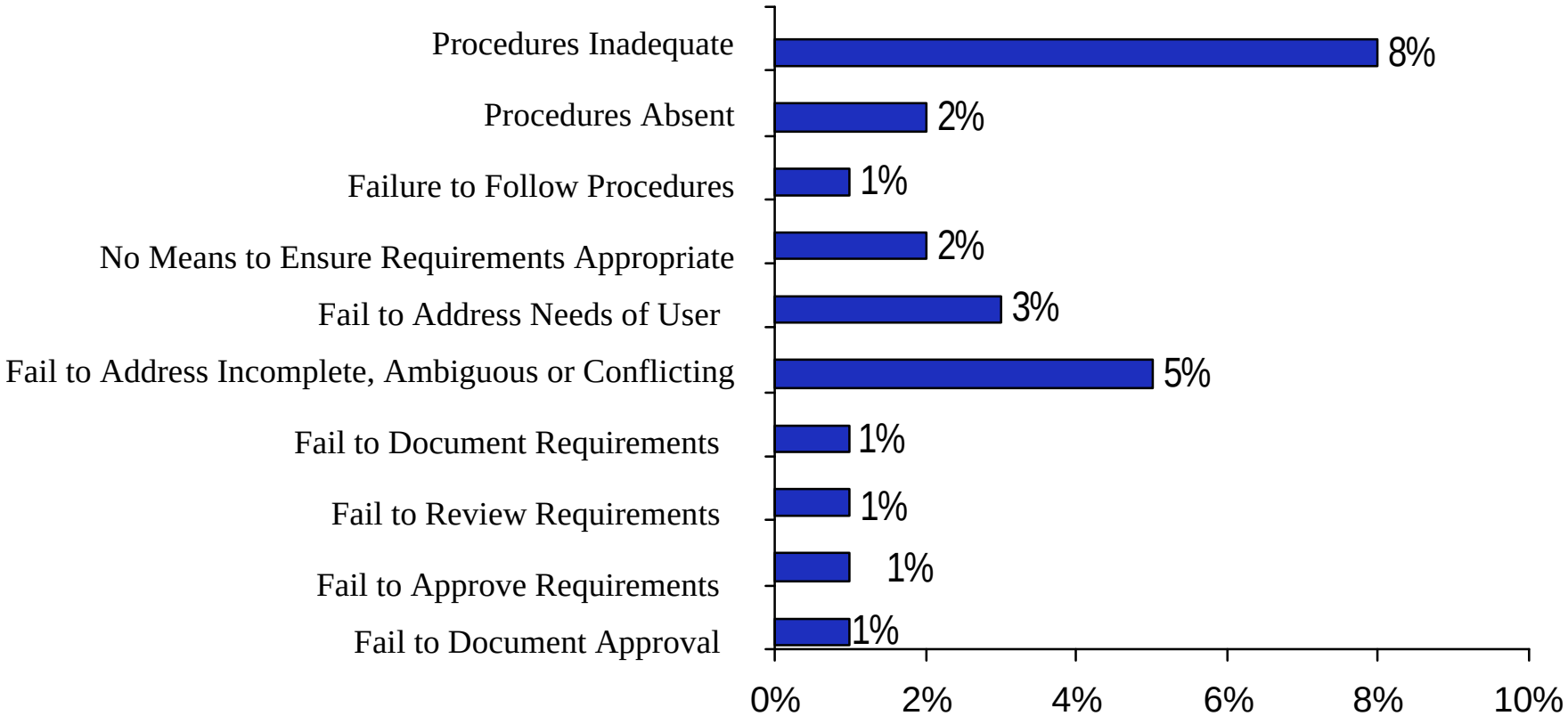
Total Firms w/ Deviations = 186

Design and Development Plan Requirements Potential Deviations



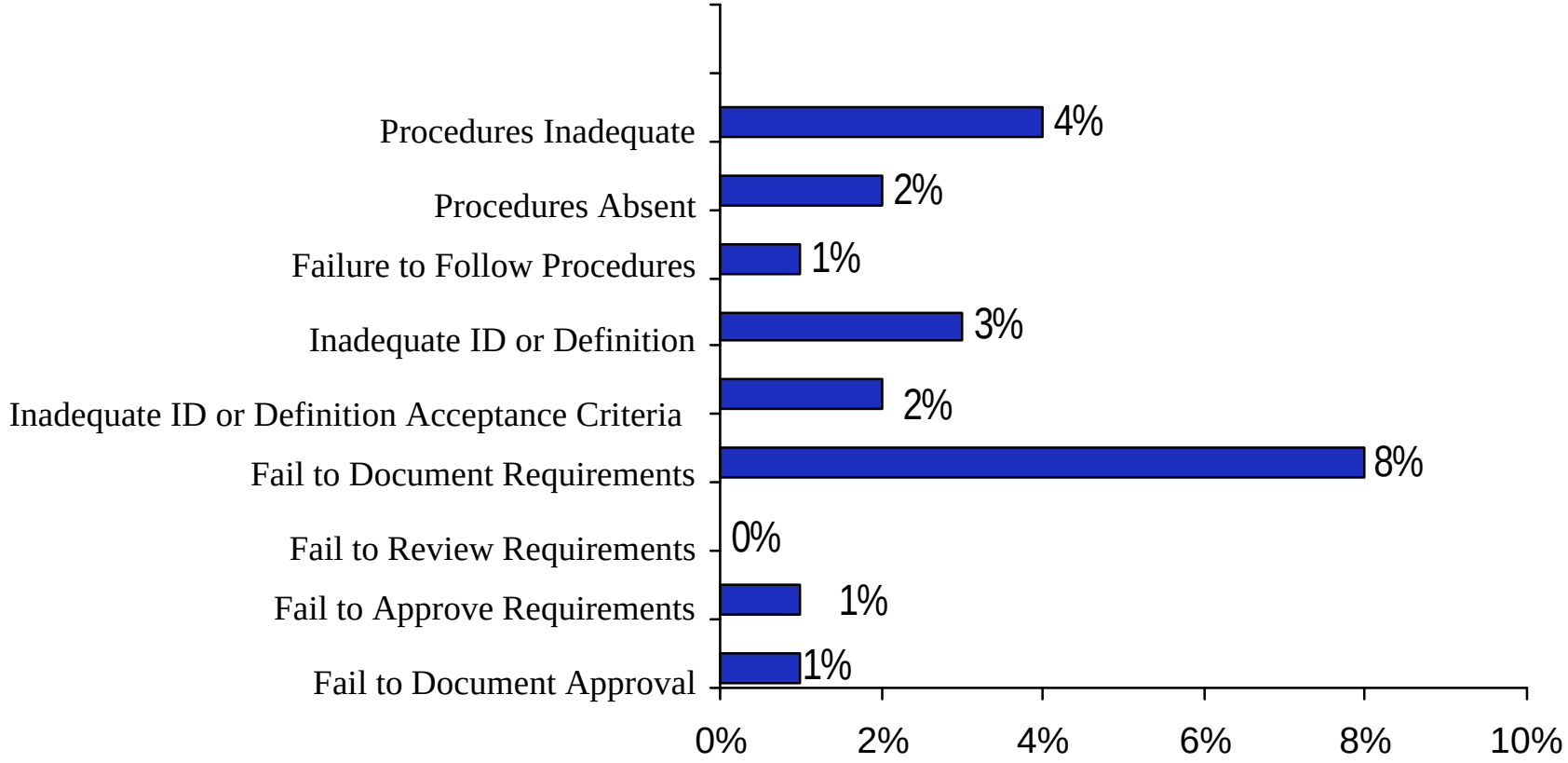
Total Firms = 582

Design Input Requirements Potential Deviations



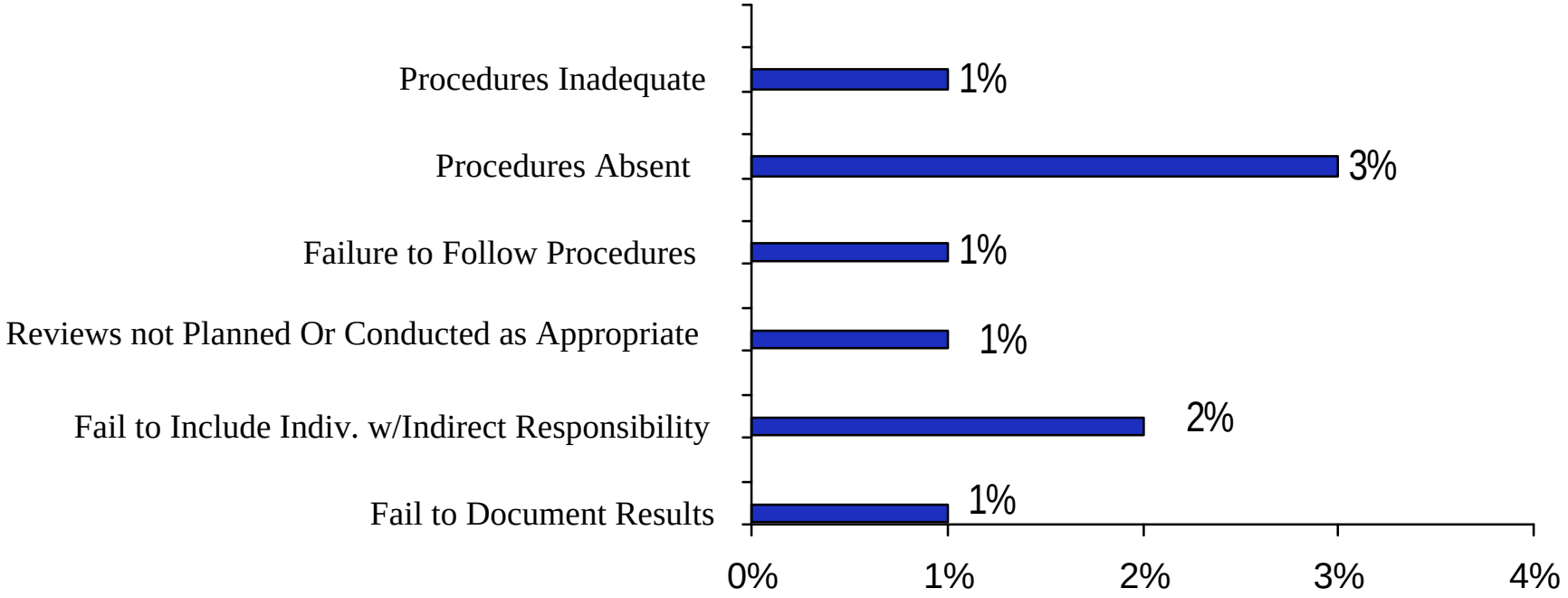
Total Firms = 582

Design Output Requirements Potential Deviations



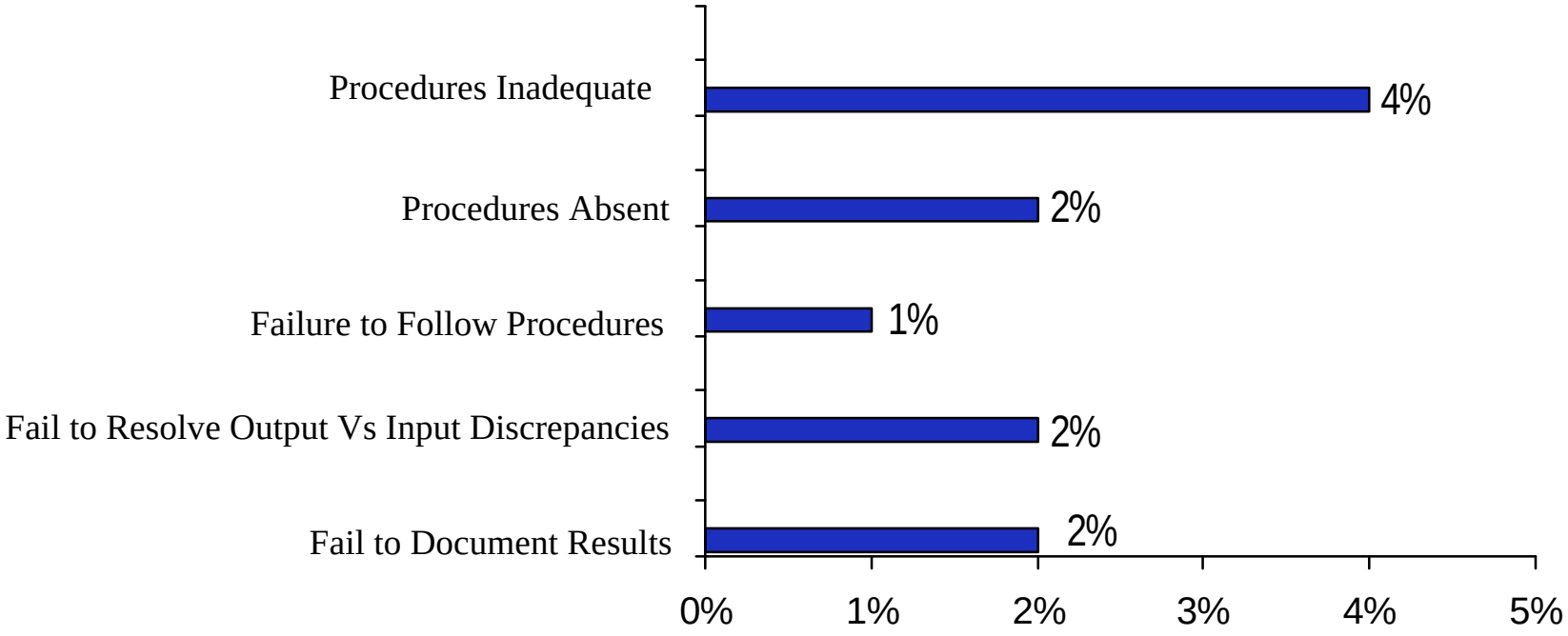
Total Firms = 582

Design Review Requirements Potential Deviations



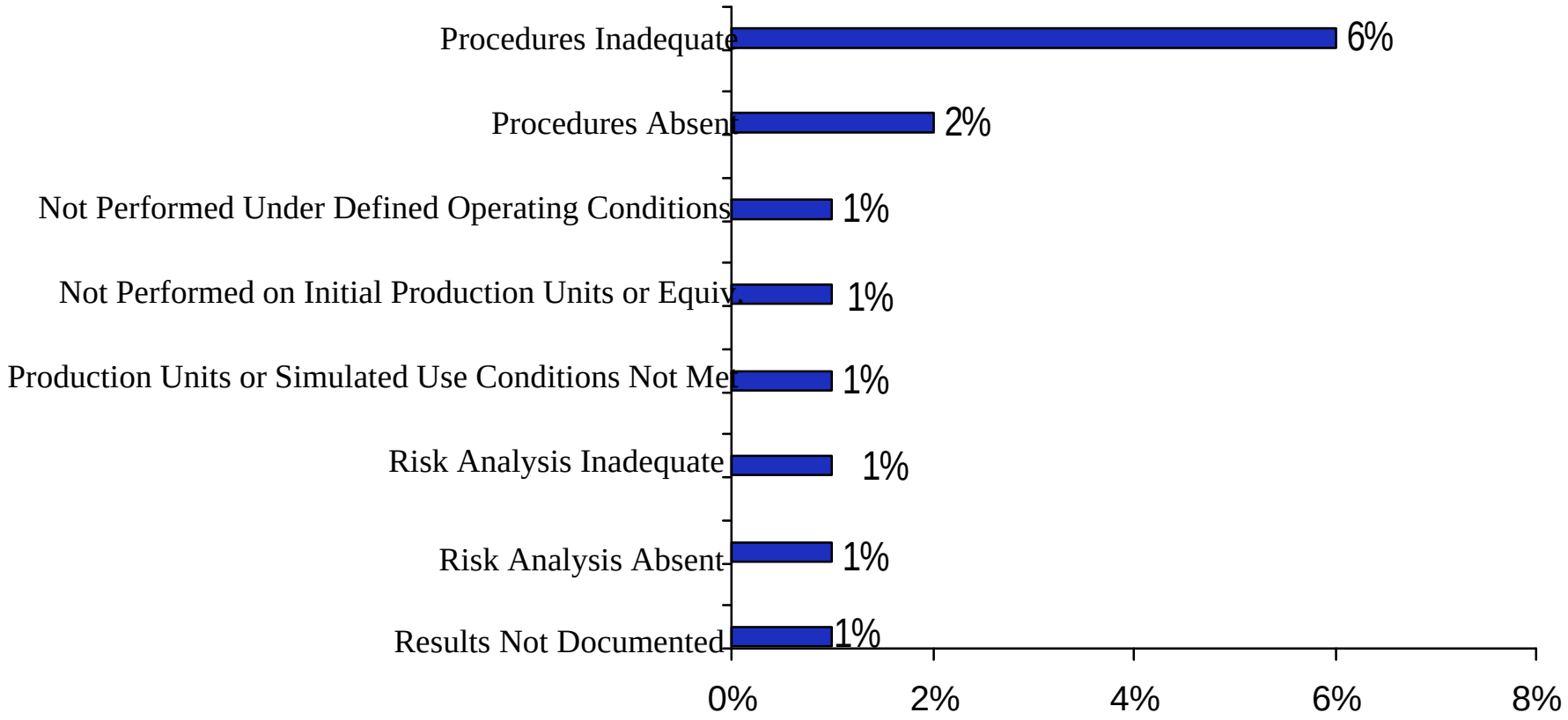
Total Firms = 582

Design Verification Requirements Potential Deviations



Total Firms = 582

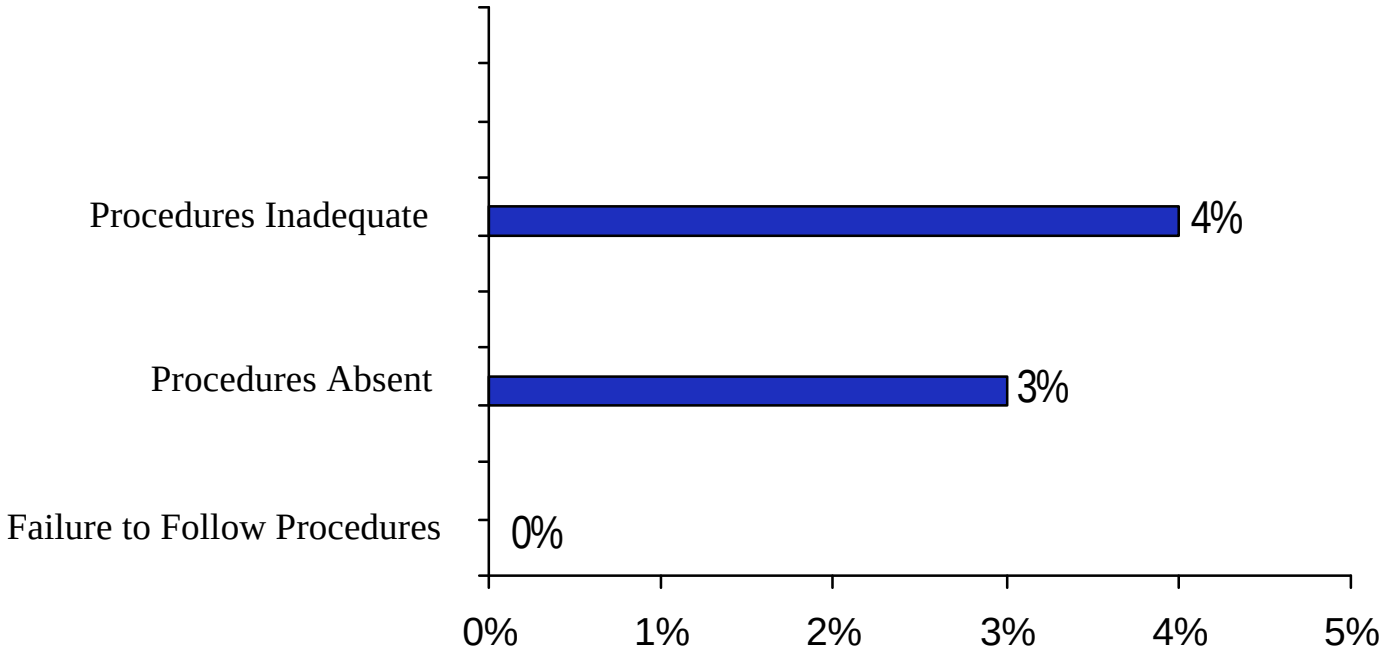
Design Validation Requirements Potential Deviations



Total Firms = 582

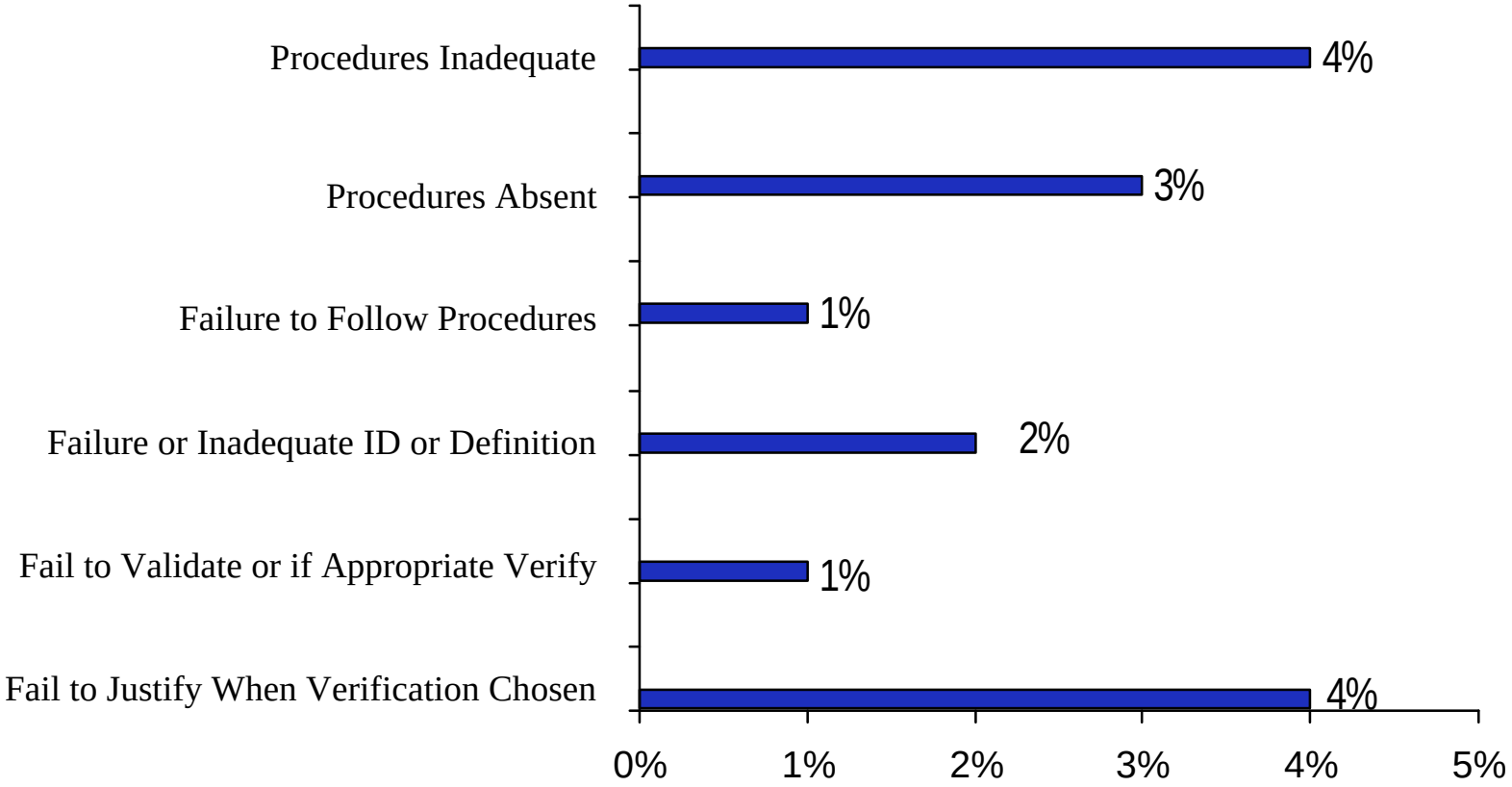
Data Collected from Areas of Needed Improvement on Design Control Reports

Design Transfer Requirements
Potential Deviations



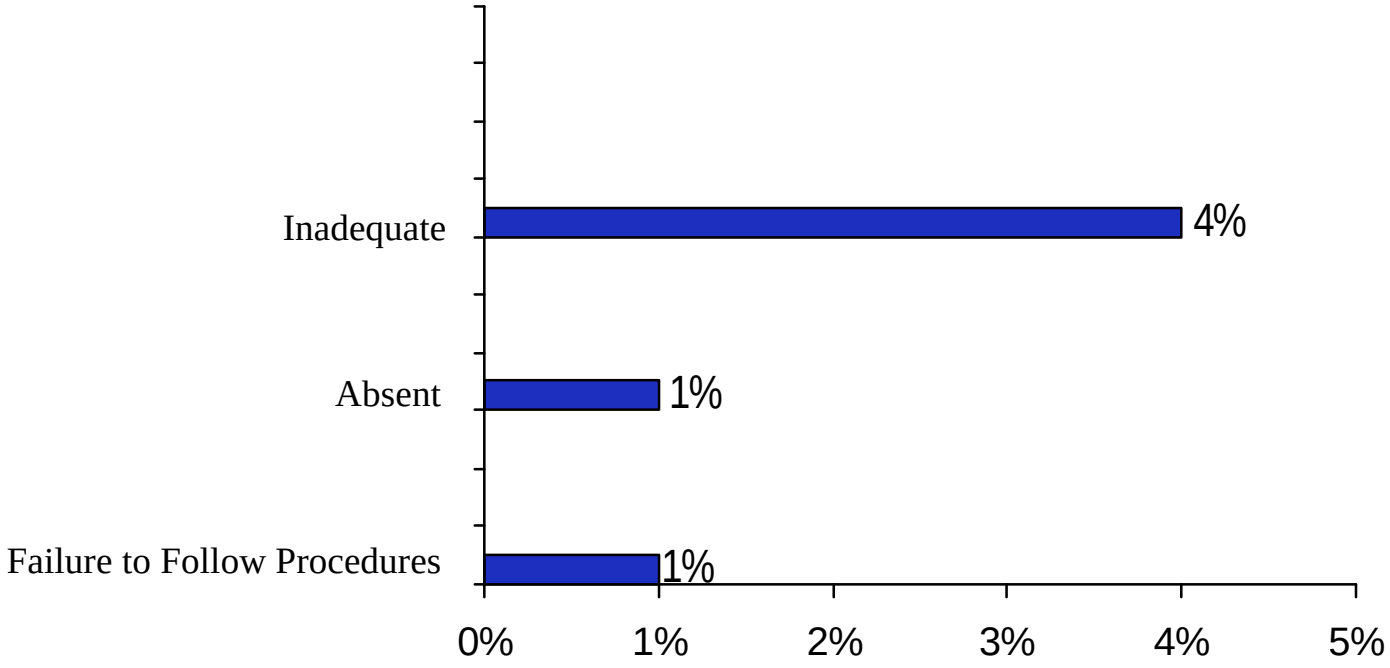
Total Firms = 582

Design Change Requirements Potential Deviations



Total Firms = 582

Design History File Requirements Potential Deviations



Total Firms = 582